



Billing Code 4410-09-M

DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
IMPORTER OF CONTROLLED SUBSTANCES
NOTICE OF APPLICATION

Pursuant to 21 USC § 958(i), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in schedule I or II, and prior to issuing a regulation under 21 USC § 952(a)(2) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with 21 CFR § 1301.34(a), this is notice that on January 5, 2012, Capricorn Pharma Inc., 6900 English Muffin Way, Unit A, Frederick, Maryland 21703, made application to the Drug Enforcement Administration (DEA) to be registered as an importer of Fentanyl (9801), a basic class of controlled substance listed in schedule II.

The company plans to import the listed controlled substance in finished dosage form (FDF) from foreign sources for analytical testing and clinical trials in which

the foreign FDF will be compared to the company's own domestically manufactured FDF. This analysis is required to allow the company to export domestically manufactured FDF to foreign markets.

In reference to the import of Fentanyl (9801), the authorization for the import of this basic class of controlled substance, if approved, would be granted only for analytical testing and clinical trials. This authorization does not extend to the import of a finished FDA approved or non-approved dosage form for commercial distribution in the United States.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances may file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR § 1301.43, and in such form as prescribed by 21 CFR § 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrisette Drive, Springfield, Virginia 22152; and must be filed no later than [insert date 30 days from date of publication].

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR § 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the Federal Register on September 23, 1975, 40 FR 43745-46, all applicants for registration to import a basic class of any controlled substance in schedules I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 USC § 958(a); 21 USC § 823(a); and 21 CFR § 1301.34(b), (c), (d), (e), and (f) are satisfied.

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration

DATED: March 8, 2012

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